

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

PAUL EVANS, Individually and on Behalf of
All Others Similarly Situated,

Plaintiff,

v.

FREQUENCY THERAPEUTICS, INC. and
DAVID L. LUCCHINO,

Defendants.

Case No. 1:21-cv-10933

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

Plaintiff Paul Evans (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, alleges the following based upon personal knowledge, as to Plaintiff and Plaintiff’s own acts, and upon information and belief, as to all other matters, based on the investigation conducted by and through Plaintiff’s attorneys, which includes, among other things, a review of U.S. Securities and Exchange Commission (“SEC”) filings made by Frequency Therapeutics, Inc. (“Frequency” or the “Company”), analyst and media reports, and Company press releases. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein.

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities action on behalf of a class consisting of all persons who purchased or otherwise acquired Frequency’s common stock between November 16, 2020, and March 22, 2021, inclusive (the “Class Period”) seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”). This action brings claims against Defendants Frequency and Frequency’s Chief Executive Officer (“CEO”) David L. Lucchino (“Lucchino”), and seeks to recover damages caused by Defendants’ violations of the Exchange Act.

2. Frequency is a publicly-traded pharmaceutical company. Headquartered in Woburn, Massachusetts and incorporated in Delaware, Frequency is focused on the development and commercialization of a hearing loss treatment titled “FX-322,” which the Company has long promoted as a potential treatment for patients with severe sensorineural hearing loss (“SNHL”).

3. Frequency has conducted multiple clinical trials assessing the safety and efficacy of FX-322, the most significant of which was a Phase 2a trial, which began in October 2019. Each participant in the Phase 2a trial was given a four-dose regimen of FX-322 (or a placebo), which

consisted of a single injection of the drug (or placebo) four weeks in a row. Frequency then assessed the results 90 days after completion of the regimen and again in the months after.

4. Shortly thereafter, Defendants Frequency and Lucchino learned that the Company's Phase 2a trial results failed to live up to the Company's expectations as the results revealed no discernable difference between FX-322 and the placebo.

5. In spite of the disappointing results, the Company continued to conduct the Phase 2a study while releasing positive statements in earnings calls, press releases, SEC filings, and pharmaceutical presentations about FX-322's potential. These statements materially misled the market and artificially inflated the value of Frequency's common stock.

6. Seizing on the Company's artificially high share price, in April 2020 Defendant Lucchino began selling his shares of Frequency, initially dumping between 10,000 and 20,000 shares—earning hundreds of thousands of dollars—each month and then increasing the number of sales to 60,000 to 80,000 shares—earning millions of dollars—each month as Frequency's deadline for releasing the disastrous Phase 2a results drew near. All told, Lucchino sold over 350,000 shares and earned over \$10.5 million.

7. Upon revelation of the disastrous results before the market opened on March 23, 2021, Frequency's shares fell from \$36.29 to \$7.99, a 78% drop, and a loss of approximately \$955 million in the Company's market capitalization.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

10. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). At all relevant times, Frequency was headquartered and conducted business in this District at 19 Presidential Way, 2nd Floor, Woburn, Massachusetts 01801. In addition, many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

11. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mail, interstate telephone communications, and facilities of national securities markets. All of the transactions in the securities that are at issue in this action took place within the United States.

PARTIES

A. Plaintiff

12. Plaintiff purchased Frequency shares at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

B. Defendants

13. Defendant Frequency is a pharmaceutical company based in Woburn, Massachusetts and incorporated in Delaware. Frequency's business is primarily focused on the development and commercialization of a hearing loss treatment called "FX-322." Frequency's stock trades on the Nasdaq Global Select Market ("Nasdaq") under the ticker "FREQ."

14. Defendant Lucchino is Frequency's CEO and President and is a director of the Company.

15. Frequency and Lucchino are collectively referred to herein as “Defendants.”

SUBSTANTIVE ALLEGATIONS

16. Founded in 2014, Frequency went public in October 2019. The Company has never earned a profit in any fiscal year and is heavily dependent on the success of FX-322, its lead product candidate. FX-322 is a treatment Frequency is developing for patients with severe sensorineural hearing loss—or SNHL.

17. A successful treatment for SNHL would be extremely lucrative. In their IPO offering documents, Frequency explained that they are motivated to develop FX-322 because the U.S. Food and Drug Administration has yet to approve any drug therapies for the treatment of SNHL.

18. Frequency has performed at least six clinical trials of FX-322; one was exploratory and tested whether FX-322 was therapeutically possible; four were Phase 1 studies and tested whether FX-322 is safe; and one study was a Phase 2 trial, which tested whether FX-322 is effective. It is this latter clinical trial—a Phase 2a study—that is at issue here.

19. The Phase 2a study began enrolling patients in the fall of 2019. In total, patients received four injections over the course of four consecutive weeks of either FX-322 or a placebo and then Frequency assessed the results in its patients 90 days later and again over the course of several more months.

20. In sum, Frequency enrolled 95 patients, with the first patient receiving the first dose at the beginning of October 2019 and the last patient receiving their first dose in September 2020.

21. Concurrently with the start of the Phase 2a study, in its 3Q 2019 Form 10-Q issued on November 18, 2019, Frequency announced that it would release the results obtained from the study “in the second half of 2020.”

22. Unfortunately, the results Frequency obtained were not positive and the Company pushed back the deadline to release the results to the spring of 2021, blaming the delay on the ongoing COVID-19 pandemic in its FY 2019 Form 10-K filed on March 26, 2020. At this point, Frequency explained, the trial was “approximately at the halfway point of enrollment.”

23. Almost immediately after, Defendant Lucchino, Frequency’s CEO, began selling his shares, dumping 5,236 shares of Frequency in his first reported sale ever on April 15, 2020.

24. Two days later he sold again, selling 3,100 shares. All told, in the month of April 2020, Lucchino sold 10,475 shares, earning over \$163,000.

25. The following month, Lucchino sold again, selling 20,953 shares, and earning over \$355,000.

26. Lucchino continued methodically selling his shares throughout the rest of the year and the first three months of 2021, increasing the pace of his sales dramatically in December 2020 to over 84,000 shares (earning approximately \$2.9 million) as the deadline for releasing the Phase 2a results neared. All told, Lucchino sold over 350,000 shares of Frequency’s common stock, earning over \$10.5 million.

27. Throughout 2020, however, Defendants painted a rosy picture of FX-322, the Phase 2a trial, and the Company’s likelihood of success.

28. For example, in a November 16, 2020 press release accompanying 3Q 2020 results, the Company boldly announced that it was “**expanding** its FX-322 development program to evaluate FX-322’s clinical profile in other SNHL patient types . . . in order to identify the broadest population that may benefit from the product candidate” and that “[t]he results of the Phase 2a end of study analysis . . . are expected to provide the basis for an end of Phase 2 meeting with the US Food and

Drug Administration regarding potential pivotal studies of FX-322,” both critical milestones in new drug development.

29. In that same press release, Defendant Lucchino added:

This past quarter we continued to gain momentum, completing study enrollment and moving toward a day-90 readout of the Phase 2a study of FX-322, while expanding our development program by adding additional studies to further our understanding of the potential of FX-322 to help the broadest SNHL patient population. The analysis of day-90 data will enable us to evaluate our key goals for the Phase 2a study and provide a comparison to the hearing improvement signal we observed in our Phase 1/2 study.

30. Later, in a January 19, 2021 conference call dedicated to FX-322’s ongoing clinical studies, Carl LeBel, Frequency’s chief development officer, compared the current Phase 2a study to one of the Company’s prior Phase 1 safety studies, explaining:

[T]hat over the course of the 90 day study, after a single injection, *there's a very good separation between the FX 322 groups and the placebo group, there's no placebo effect to really speak of and these effects were statistically significant as well.*

...

So here, we're essentially seeing that a single injection of FX 322 can keep a benefit manifest by improvements in word recognition almost 1 to 2 years later depending on the subject and that's really quite remarkable, we can't think of a single example where one gives a small molecule or one injection and sees an effect, a biologic effect that can be maintained for that long. So really exciting data.

So all the learnings from the phase 1 study of the durability data, we carry forward into a phase 2a study and this is the study that is running now, it was enrolled—fully enrolled in the September of last year. It has a similar design, same kinds of patients that have to have stable hearing loss, they have to have etiologies that are noise-induced or some sensorineural, they have to have baseline recognition deficits, word recognition deficits and that way, every patient in the study has a benefit, has an opportunity to see a benefit if they have been assigned to FX 322.

31. Unfortunately, the Phase 2a study was not going well, a fact Defendants knew well, and which the investing public market would learn soon.

THE TRUTH EMERGES

32. Before the market opened on Tuesday, March 23, 2021, Frequency disclosed in a press release deeply disappointing interim Phase 2a results, revealing that subjects with mild to moderate SNHL ***did not*** demonstrate improvements in hearing measures versus placebo.

33. These results dramatically undercut the narrative the Company had spun since Frequency's IPO and investors reacted accordingly. That day, Frequency's shares fell from \$36.29 to \$7.99, a 78% drop, representing a decline in the Company's market capitalization of approximately \$955 million.

34. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and the other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all those who purchased or otherwise acquired Frequency's common stock during the Class Period and were damaged upon the revelation of the alleged corrective disclosure (the "Class"). Excluded from the Class are the Defendants named herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Frequency's common stock was actively traded on the Nasdaq in the United States. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are

hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Frequency or its transfer agent and/or the Nasdaq and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of Frequency;
- (c) whether the Defendants Lucchino caused Frequency to issue false and misleading statements during the Class Period;
- (d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

- (e) whether the prices of Frequency's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- (f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable.

41. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

PRESUMPTION OF RELIANCE

42. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) the omissions and misrepresentations were material;
- (c) Frequency's common stock is traded in an efficient market;
- (d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- (e) the Company's securities were traded on the Nasdaq in the United States;
- (f) the Company was covered by securities analysts;
- (g) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(h) Plaintiff and members of the Class purchased, acquired, and/or sold Frequency's common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed without knowledge of the omitted or misrepresented facts.

43. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

44. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I
Violations of §10(b) of the Exchange Act and Rule 10b-5
(Against All Defendants)

45. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

46. This Count is asserted against Defendants and is based upon §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

47. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and,

throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Frequency's common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Frequency's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

48. Pursuant to the above plan, scheme, conspiracy, and course of conduct, Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases, and other statements and documents, as described above, including statements made to securities analysts and the media, that were designed to influence the market for Frequency's common stock. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Frequency's business and operations.

49. By virtue of their positions at Frequency, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted, as described above.

50. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As a senior manager and/or

director of Frequency, Defendant Lucchino had knowledge of the details of Frequency's internal affairs.

51. Defendant Lucchino is liable both directly and indirectly for the wrongs complained of herein. Because of his position of control and authority, Defendant Lucchino was able to, and did, directly or indirectly, control the content of the statements of Frequency. As an officer and/or director of a publicly held company, Defendant Lucchino had a duty to disseminate timely, accurate, truthful, and complete information with respect to Frequency's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Frequency's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Frequency's business and financial condition, which were concealed by Defendants, Plaintiff and other members of the Class purchased or otherwise acquired Frequency's common stock at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or statements disseminated by Defendants, and were damaged thereby.

52. During the Class Period, Frequency's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired Frequency's common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired shares at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff

and the Class, the true value of Frequency's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Frequency's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

53. By reason of the conduct alleged herein, Defendants have knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

54. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of §20(a) of the Exchange Act
(Against Defendant Lucchino)

55. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

56. During the Class Period, Defendant Lucchino participated in the operation and management of Frequency and conducted and participated, directly and indirectly, in the conduct of Frequency's business affairs. Because of his senior position as the Company's CEO and President, Defendant Lucchino knew of the adverse non-public information alleged herein.

57. As an officer and/or director of a publicly owned company, Defendant Lucchino had a duty to disseminate accurate and truthful information, with respect to Frequency's business practices, and promptly correct any public statements issued by Frequency that had become materially false or misleading.

58. Because of his position of control and authority as a senior director and/or officer and/or executive team member, Defendant Lucchino was able to, and did, control the contents of the various reports, press releases, and public filings that Frequency disseminated in the marketplace during the Class Period concerning the Company's business, operational, and disclosure policies. Throughout the Class Period, Defendant Lucchino exercised his power and authority to cause Frequency to engage in the wrongful acts complained of herein. Defendant Lucchino therefore, was a "controlling person" of Frequency within the meaning of §20(a) of the Exchange Act. In this capacity, Defendant Lucchino participated in the unlawful conduct alleged herein that artificially inflated the market price of Frequency's common stock.

59. Defendant Lucchino, therefore, acted as a controlling person of Frequency. By reason of his senior management position and/or being a director of Frequency, Defendant Lucchino had the power to direct the actions of, and exercised the same, to cause Frequency to engage in the unlawful acts and conduct complained of herein. Defendant Lucchino exercised control over the general operations of Frequency and possessed the power to control the specific activities that comprise the primary violations about which Plaintiff and the other members of the Class complain.

60. By reason of the above conduct, Defendant Lucchino is liable pursuant to §20(a) of the Exchange Act for the violations committed by Frequency.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and relief as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23 and certifying Plaintiff as Class Representative;

- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED this 3rd day of June, 2021.

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